DETAILED ACTION

The finality of the action mailed 12/23/08 is withdrawn and this action replaces it. This Final Rejection adds an objection for Sequence rules and a rejection based on the sequence.

Claims 34-65 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-42, and 45-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al*. (J of Virology Vol 75, pages 6154-6165, from IDS) and Saito *et al*. (Vaccine 2001 Vol. 20 pages 125-133).

Applicant argues the following:

That the VLPs are structurally different from Latham et al., and that the VLPs have the unexpected property of increased production in SF9 cells as supported by the Smith declaration (see below), that it is an improper obvious type rejection and that the examiner has mistakenly used inherency analysis in the rejection (concerning In re Napier).

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant and declaration refer to the VLPs of Latham et al. The rejection is based on two references and the obviousness to combine (see Non-Final Action 2/10/06, page 5, last paragraph) and was maintained or modified as necessitated by amendment.

The declaration states in Para#2 states that they know the legal conclusions drawn by the examiner and have reviewed Latham et al. This is not commensurate with the rejection because as stated above and in the Office actions, there are two references used in the rejection.

The declaration states in Para#4 "superior for the production of VLPs", The claims do not require "production", they are drawn to a product, not a method.

The declaration discusses in Para#3-11 that there is a difference in seasonal human and avian influenza M1 proteins and discusses experiments and mutations used to show the increased production of VLPs. As noted above, the claims are drawn to a product, not a method of making. Applicant has not shown or demonstrated that there is a difference in making the human versus avian influenza VLPs that would show that it was not obvious to succeed in combining Latham et al. and Saito et al.

As far as the motif recited in the new claims that applicant discusses in the declaration, that sequence is found in the M1 of Saito et al., see Influenza A virus M1A/Hong Kong/1073/99(H9N2) NCBI ACCESSION# AAK49233.

Applicant argues that the inherency cannot be shown with post filing publications and that the examiner does not have knowledge that the VLPs of Latham et al. have activity and this knowledge is required for the rejection. The examiner does not have the abilities to test the VLPs and has properly shifted the burden to applicant. Applicant is arguing the HA and NA activity of the VLPs as a functional limitation required for a method not as a property of the product. Applicant has not presented any evidence that the product was not obvious over the prior art.

Applicant argues that retrospective inherency is not a substitute for some teaching to support an obviousness rejection. Knowing that the VLPs have activity is not a reason used to combine the references by the examiner. The activity is a property of the product VLP made by the process of Latham et al. and neither applicant nor the post filing art cited has shown any reason to doubt the product VLP has the property.

The post filing art was used to show the property, not to provide retrospective motivation.

As far as the properness of inherency in the 103 rejection, Applicant appears to be construing the inherency as limiting the rejection to one reference or that the VLP that is obvious from the prior art is only Latham et al. The examiner cannot argue the law of a 102 rejection when the rejection at hand is a 103.

Thus, the claims are unpatentable over Latham *et al.* and Saito *et al.*

Rejection Maintained

Claim Rejections - 35 USC § 103

Claims 34, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* and Saito *et al.* as discussed above and Gupta *et al.* (Vaccine 2001 Vol. 14 pages 219-225).

Applicant argues that Latham et al. does not teach activity and that Saito et al. or Gupta et al. do not cure the defects. .

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As far as the claim limitation of enzymatic activity, it is discussed above and applicant has not differentiated the product made in the rejection versus the claimed product.

The rejection is maintained.

Rejections Necessitated By Amendment

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID#s) in all locations where sequences are recited, see claims 64 and 65. Applicant needs to submit a new CRF, paper copy and statement the includes the recited peptide.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

Claim Rejections - 35 USC § 112

Claims 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 64 and 65 recite a peptide. Applicant points to a declaration filed to show that the peptide is in the nucleic acid used in the specification. That would be support if

the protein as a whole were used and only that protein but in the context of the present claims, support is required for the peptide itself.

Applicant is requested to point to support that demonstrates that at the time of invention that peptide was contemplated in particular. The mere fact that the sequence used contains the recited sequence does not provide the support for the claim as written.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M,W,F, and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. G. H./
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648